

NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled Wal-Mart Stores Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

NIGHTTIME SLEEP-AID

Drug Facts

Active ingredients (in each softgel)

Diphenhydramine HCl 25 mg

Purpose

nighttime sleep-aid

Uses

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

Ask a doctor or pharmacist before use if you are taking sedatives, tranquilizers or any other sleep aid

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. Overdose warning: Taking more than directed can

cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 1(800)222-1222

Directions

- **do not take more than directed**
- take only one dose per day (24 hours)

adults & children 12 yrs & over	One dose= TWO 25 mg softgels (50 mg) at bed time if needed or as directed by a doctor
children under 12 years	Do not use

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F) and high humidity
- Protect from light

Inactive ingredients

FD&C Blue#1, FD&C Red#40, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-287-1915

DISPLAY PANEL

EQUATE

NIGHTTIME

SLEEP-AID

DIPHENHYDRAMINE HCl 25 mg

Non Habit-Forming

Not for Treating Pain, Cold or Flu



NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79903-083
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients				
Ingredient Name			Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	purple	Score	no score	
Shape	CAPSULE (OBLONG)	Size	15mm	
Flavor		Imprint Code	602	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903-083-01	1 in 1 CARTON	06/22/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:79903-083-02	2 in 1 CARTON	06/22/2021	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part338	06/22/2021		

Labeler - Wal-Mart Stores Inc (051957769)

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Wal-Mart Stores Inc